

No. 82225-5

SUPREME COURT OF THE STATE OF WASHINGTON

CITY OF PORT ANGELES, Respondent,
v.
OUR WATER-OUR CHOICE, and PROTECT OUR WATERS,
Petitioners,

v.
WASHINGTON DENTAL SERVICE FOUNDATION, LLC,
Respondent.

CORRECTED

AMICI CURIAE BRIEF OF INTERNATIONAL ACADEMY OF ORAL MEDICINE AND TOXICOLOGY, OREGON CITIZENS FOR SAFE DRINKING WATER, FLUORIDE ACTION NETWORK, WASHINGTON ACTION FOR SAFE WATER, WHIDBEY ENVIRONMENTAL ACTION NETWORK, AUDREY ADAMS, LINDA MARTIN, BILL OSMUNSON DDS, MPH, GERALD H. SMITH MD, AND FLUORIDE CLASS ACTION

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I. IDENTITY AND INTEREST OF AMICI CURIAE

The Amici Curiae are International Academy of Oral Medicine and Toxicology, Oregon Citizens for Safe Drinking Water, Fluoride Action Network, Washington Action for Safe Water, Whidbey Environmental Action Network, Audrey Adams, Linda Martin, Bill Osmunson DDS, MPH, Gerald H. Smith MD, and Fluoride Class Action. The interests of each group are set forth in Appendix A.

II. ISSUES ADDRESSED

This Amici Curiae Brief addresses Issues 1 to 5 presented in the Petition for Review at 1-2.

III. BRIEF STATEMENT OF THE CASE

The two Initiatives of the Petitioning Committees (Initiatives) would prohibit putting medication, including fluoride, into Port Angeles water. Amici support Petitioners, referred to as the Committees, request that these Initiatives be allowed on the ballot. Adding medication to City water in the form of fluoride causes immediate harm to some people and long-term harm to many more. This is an assault by government, an infringement on liberty and privacy, a taking of property without compensation, and an infringement on the practice of religion. Not allowing the electorate to vote on the Initiatives violates First Amendment rights to free speech and to petition one's government. The citizens of Port Angeles deserve the right to vote on these issues.

IV. A HISTORY OF THIS CASE

This case proceeded oddly during its trial phase.

There was no trial. The Trial Court treated the case as a summary judgment motion. No one testified; counsel merely argued. For facts, the judge relied on attorney declarations. The two sides did not submit stipulated facts. See Findings of Fact, Conclusions of Law, and Judgment at 3.2.

No experts gave their professional opinion to assist the Trial Court in taking judicial notice of legal-scientific matters. No scientific journal articles were brought in and added to the file.

The Trial Court made no findings regarding the allegations in the two Initiatives.

The Initiatives, incorporated as part of the Complaints, raised serious allegations that fluoridation is harmful immediately to some people and harmful over a lifetime to others. However, counsel and Trial Court ignored these allegations, perhaps because "experts" on initiative suits like this say the courts do not care about health or constitution issues and that the parties should debate only the legislative v. administrative question.

Although this was a trial about two initiatives, Counsel and Trial Court ignored the content of those initiatives, including its allegations of harms to health and and violations of the Constitutional.

Counsel and Trial Court ignored whether there was any truth to the allegation that fluoride was bad for babies, for kidney patients, for diabetics, for seniors with weak bones, bad for making teeth mottled.

If health is really harmed by water fluoridation, then it is an assault, and if that assault is committed by a government entity, there is a violation of Constitutional rights. If something is unconstitutional, then it is easy to conclude that the issue is legislative, because the Committees are merely trying to vote to stop unconstitutional acts and enforce currently unenforced laws.

The legislative v administrative issue is not always fundamental. In a case like this, it is merely a reflection of more substantive issues.

Counsel and Trial Court ignored First Amendment issues. The First Amendment says:

Congress shall make no law ... abridging the freedom of speech or the right of the people ... to petition the Government for a redress of grievances.

Although the Initiatives are not labeled as "petitions," that is what they are. The people are petitioning their government to allow them to vote to correct a "grievance." For these petitions to be meaningful, the grievance, if genuine, should be redressed. Redress in this case would mean putting the Initiatives on the ballot.

Whether fluoridating drinking water is a grievance is a legal-scientific issue. This why the Court should study the basic scientific issues in order to decide this case.

The Amici in this brief present enough citations from enough authoritative scientific sources that this Court could take judicial notice that fluoridation is harmful to some and may in fact be ineffectual in preventing tooth decay.

The proposed Water Additives Safety Act specifically referenced the following statutes and regulations: FDA Act, RCW 35.88.020, RCW 35A.70.070(6), RCW 70.142.010, and WAC 246-895-070. The Court made no findings regarding these issues. "Statutory interpretation and the question of whether a statute applies to a particular set of facts are issues of law reviewed de novo." In re Dependency of T.L.G., 139 Wash.App. 1, 156 P.3d 222 (2007) at paragraph 22.

It is clear from the Clerks Papers that the "trial" was handled as a summary judgment motion. (Verbatim Report of Proceedings, Dec 11, 2006, p. 5, line 13.) This means this Court may review it de novo.

The Initiatives raised constitutional issues. The proposed Water Additives Safety Act referenced Washington Constitution Section 11, Article 11. The proposed Medical Independence Act mentioned access to public water as a property right taken without compensation, the right to control one's own medical care, the right to informed consent for medical treatment, and the "pursuit of life

and liberty." The City was put on notice regarding these constitutional claims.

The Trial Court made no findings regarding these issues.

These would be new assignments of error. RAP 2.5 provides that "a party may raise the following claimed errors for the first time in the appellate court: ... manifest error affecting a constitutional right." This being the constitutional court of Washington, the Amici urge the Court to excuse that these considerations are being brought forward at this late date and consider these constitutional issues.

V. A JUDICIOUS THING TO DO

The amici urge the Court to rule in favor of the Committees. There is more than enough evidence in their favor for the Court to do so. Trial Courts ought to make findings on all material issues, and the Trial Court in this case failed to do that. Frank A. Peterson v. William E Neal, 48 Wn.2d 192, 292 P.2d 358 at 194-195.

VI. JUDICIAL NOTICE OF WELL-KNOWN SCIENTIFIC FACTS

This Court in Houser v. State stressed the importance of taking judicial notice of scientific studies. ER 201 provides that the Court may take judicial notice at any stage of the proceeding. Amici ask the Court to take judicial notice of the scientific

¹ This Court said that it was obligated to: "look beyond the case reports and statute books into a world that is rich with probability and conjecture and almost devoid of settled certainty. It must make the best assessment it can from the best information it can obtain. Reputable scientific studies are one source of such information, increasingly utilized by courts in constitutional decision making." 85 Wn.2d 803, 540 P.2d 412 at 807 (1975) at 807.

facts listed in this section. Most of the scientific facts cited here come from Fluoride in Drinking Water: A Scientific Review of EPA's Standards, a 2006 report prepared by the National Research Council, a branch of the National Academy of Sciences, the most prestigious and authoritative research institute in the country, referred to herein as the "2006 NRC Report."

People drink widely varying amounts of water. Babies drink 2.5 times as much water per pound of body weight as adults.² Five percent of the population drinks 3.5 liters of water per day on average and one percent drinks 6.09 liters, thus getting 3.5 mg to 6.09 mg of fluoride when water is fluoridated to a level of 1.0 mg per liter or 1.0 ppm. Children who play, athletes, workers who sweat, those with kidney disease, and diabetics may drink this much or more. See 2006 NRC report p. 381. See Appendix D-1.

In the July, 2000, cover story of the prestigious Journal of the American Dental Association, Dr. John Featherstone, citing numerous other mainstream scholarly journals, explains that fluoride works primarily topically and not systemically.³ The CDC in its MMWR publication praises water fluoridation, but it

 $^{^2}$ "[S]ome members of the U.S. population could have intakes from community water sources of as much as 4.5-5.0 L/day (as high as 80 mL/kg/day for adults. Some infants have intakes of community water exceeding 200 mL/kg/day." See 2006 NRC Report p. 25. See Appendix D-2.

³ "The fluoride incorporated developmentally – that is, systemically into the normal tooth mineral – is insufficient to have a measurable effect on acid solubility. [890] ... Fluoride incorporated during tooth development is insufficient to play a significant role in caries protection." [891] Dr. Featherstone points out that antibacterial mouthwash is highly effective in preventing caries. Featherstone JDB, M.Sc., Ph.D, J American Dental Association, Vol. 131, July 2000, p. 890. See Appendix D-3. See Background: CDC, Infant Formula and the Risk for Enamel Fluorosis, CDC, www.cdc.gov/fluoridation/safety/infant formula.htm, attached as Appendix D-16.

too still admits that the effect of fluoride is primarily topical.⁴ This means that drinking fluoride to prevent decay is ineffectual. In balancing benefits and harms, the calculation is overwhelmingly negative, and this affects the constitutional calculation. At best fluoridation is a waste of money.

The mother who drinks water fluoridated at 1 ppm or 1,000 ppb nurses her baby with milk containing 9.8 ppb. The mother who drinks non-fluoridated water nurses with only 4.4 ppb. See the 2006 NRC Report, p. 27-30 attached as Appendix D-26.

World Health Organization research shows tooth decay rates in Europe, which is mostly non-fluoridated, are as low or lower than in the United States.⁵

Regarding fluoride, the EPA set a 2% secondary maximum contaminant level, SMCL, which was calculated to hold the level of moderate enamel fluorosis down to 15% of exposed population. This is an admission that water at 2 ppm causes moderate fluorosis. As pointed out above, a lot of people drink double or triple or more the average amount of water and would consume 2 mg, 4 mg, or 6 mg of fluoride per day or more. And, 15% of us should not grow up with mottled "funky teeth," as children call them. The 2006 NRC Report concluded that

⁴ "[L]aboratory and epidemiologic research suggests that fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children. Morbidity and Mortality Weekly Report, Oct 22, 1999/48(41), 933-940 at paragraph 14. See Appendix D-21. See the full article at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm.

⁵ See World Health Organization Chart at Appendix D-31. For full report see http://www.whocollab.od.mah.se/euro.html.

moderate fluorosis can affect sense of well-being.⁶ If someone fisted you in the mouth and disfigured your teeth, that would be an assault. So too is adding fluoride to water knowing that it will cause noticeable fluorosis in 15% of the drinkers.

The NRC recommended that the EPA lower the 4 ppm MCL Maximum Contaminant Level and the MCLG Maximum Contaminant Level Goal. ⁷ Three years have passed and the EPA has not acted to set a new fluoride level. Thus the voters have a right to set their own maximum level through these Initiatives. There is now no recognized safe fluoridation level. The City has no safe harbor.

Double-blind clinical studies and numerous case studies demonstrate that from one to five percent of the population, are hypersensitive to fluoride to varying degrees, and these people can experience incapacitating symptoms that can drive them to move away from cities with fluoridated water. This court stated in 1954 that if city water is fluoridated, it will be necessary for residents "to use it for domestic purposes including drinking, because there is no other practical source of supply." Kaul v Chehalis, 45 Wn.2d 616, 277 P.2d 352 (1954) at 618.

Some people cannot afford a distiller or a whole house filter. Some are not strong

⁶ 2006 NRC Report page 4. See Appendix D-32.

⁷ 2006 NRC Report pages 2 and 8. See Appendix D-33.

⁸ Dr. Bruce Spittle, M.D., Fluoride Poisoning: Is fluoride in your drinking water—and from other sources—making you sick? 2008, ISBN 978-0-473-12991-0, which can be downloaded from http://www.pauapress.com/fluoride/files/1418.pdf. See Appendix C.

enough to haul water jugs home. Some do not own a vehicle. Some cannot afford to buy water.

VII. THE STANDARD TO BE APPLIED

The SWDA describes the term "MCLG" as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." This is the standard which should be applied. Those who oppose fluoridation should not be put in the position of having to prove fluoride is harmful; those who support fluoridation should have the burden to prove it safe. Water should be as pure as possible. It should not be pure except for a little arsenic, a little lead, and a lot of fluoride. RCW 70.54.020, RCW 35.88.020.

VIII. McQUILLIN ON INITIATIVES CLARIFIES THE LAW REGARDING INITIATIVES AND REFERENDUMS.

Attached hereto as Appendix B are relevant excerpts from McQuillin, The Law of Municipal Corporations, Third Edition, 2002 Revised Volume, with July 2009 Cumulative Supplement (referred to herein as "McQuillin") regarding initiatives and referendums. McQuillin states:

The First Amendment provides that Congress shall make no law abridging freedom of speech. Because state action includes city ordinances adopted under state authority, the First Amendment prohibitions extend to local initiative and referendum procedures. McQuillin, Sec. 16:47 at page 368-70. (Citations are omitted; the full text appears in Appendix B).

IX. RCW 57.08.012 MAKES FLUORIDATION A LEGISLATIVE AND NOT AN ADMINISTRATIVE ISSUE.

RCW 57.08.012 reads as follows:

A water district by a majority vote of its board of commissioners may fluoridate the water supply system of the water district. The commissioners may cause the proposition of fluoridation of the water supply to be submitted to the electors of the water district at any general election or special election to be called for the purpose of voting on the proposition. The proposition must be approved by a majority of the electors voting on the proposition to become effective.

RCW 57.08.012 applies to water districts and not to cities, and water district commissioners are not required to submit the issue to a vote even if a vote is requested by electors. But the statute still indicates that the legislature regards the fluoridation decision as of the type or kind which can be submitted to voters.

X. THE SAFE DRINKING WATER ACT FORBIDS ENACTING REGULATIONS WHICH REQUIRE ADDING MEDICATION TO DRINKING WATER AND THIS RESTRICTION MAY FLOW DOWN TO THE STATES AND MUNICIPALITIES

The Centers for Disease Control (CDC) is the biggest proponent of drinking water fluoridation in the United States. See http://www.cdc.gov/fluoridation. The current surgeon general and many before him supported fluoridation. However, neither the CDC nor the Surgeon General has any jurisdiction over water fluoridation.

The Safe Water Drinking Act (SDWA) is administered by the EPA. Note that the SDWA specifically states at 42 USC 300g-1(b)(11):

No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water.

The only substances which the SDWA may require that states and municipalities add to their drinking water are those which remove contaminants. Substances for preventive health care may not be added. That would include drugs, medicine, and ... fluoride.

It comes as a surprise to those studying this area of the law to learn that the SDWA, regulates only the removal of contaminants which naturally appear in water or which have been added through pollution. It does authorize adding chemicals but only those which remove contaminants.

Many think that because the SDWA has a 4 ppm maximum contaminant level (MCL) for fluoride, that the SDWA authorizes the insertion of fluoride up to a 4 ppm maximum. This is not so. The SDWA only requires removal of fluoride if it exceeds 4 ppm. The 2006 NRC Report at page 1, seen at Appendix D-35, clarifies this:

In 1986, EPA established an MCLG and MCL for fluoride at a concentration of 4 milligrams per liter (mg/L) and an SMCL of 2 mg/L. These guidelines are restrictions on the total amount of fluoride allowed in drinking water. ... EPA's drinking-water guidelines are not recommendations about adding fluoride to drinking water to protect the public from dental caries. ... Instead, EPA's guidelines are maximum allowable concentrations in drinking water intended to prevent toxic or other adverse effects that could result from exposure to fluoride.

In each state there is a lead agency which is empowered to administer the SDWA, and in Washington that agency is the Department of Health. RCW 70.119A.080, RCW 43.21A.445. See Appendix D-36. As noted by the Court of Appeals in its Opinion at 7 (Petition for Review at A-7), the EPA has granted primacy to the state of Washington to implement the SDWA. 40 C.F.R. 42.10. In RCW 43.21A.445 several Washington agencies led by the Department of Health are "... authorized to participate fully in and are empowered to administer ..." the SDWA.

Because the SDWA prohibits requiring "the addition of any substance for preventive health care purposes" and because the SDWA requires that state "... drinking water regulations" be "no less stringent than the national primary drinking water regulations," Washington regulations likewise must be so limited. Therefore, the Department and Board of Health may not authorize or require municipalities to add fluoride or any other medication intended for "preventive health care purposes."

This limitation on "the addition of any substance for preventive health care purposes" flows down to the states, but does it flow down further to municipalities? 40 C.F.R. 142.3 provides:

"... [T]his part [40 C.F.R.. Part 142—National Primary Drinking Water Regulations Implementation] applies to each public water system in each State.

40 C.F.R. 142.2 defines a "public water system thus:"

Public water system or PWS means a system for the provision to the public of water for human consumption through pipes or, after August 5, 1998, other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year.

Using the wording of this federal regulation, it would appear that the Port Angeles city council enacted a "drinking water regulation" which requires "the addition of" a "substance for preventive health care purposes unrelated to contamination of drinking water," namely fluoride. If the limitations imposed by the SDWA do flow down to the City, then the City's decision to fluoridate was ultra vires, and for that reason too the electorate should have the right to vote on the two Initiatives in question — to reverse an ultra vires decision — which would make this issue legislative and not administrative.

On its face WAC 246-290-460 does not regulate the decision to fluoridate but only sets out procedures to follow if a municipality decides to fluoridate. Thus state regulations have not occupied the fluoridation field and, as well, say nothing about adding other medicines to public water supplies.

If the state has not occupied the field, there is room for the corporate City acting through its police power, and therefore the electors acting through the initiative process, to adopt ordinances that prohibit or limit anyone from putting any medications in any public water supplies serving the City. This power is explicit under RCW 35.88 and RCW 35A.70.070, and nothing in RCW

70.142 says otherwise. It is a doctrine of statutory interpretation that if statutes can be read in a way such that they harmonize with each other, they should be read that way.

The US Food and Drug Administration (FDA) should have jurisdiction over fluoride added to drinking water, simply because fluoridated water meets the definition of a drug. The Food, Drug, and Cosmetics Act (FDCA) defines a drug as an article "... intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal. 21 U.S.C. 321 (g)(1)(B). Dental caries is a disease, and fluoride is added to water to prevent caries.

However, the FDA has chosen not to assert jurisdiction over fluoride scrubber liquor in its raw state nor over the fluoride-tap water mixture called fluoridated water. The FDA has asserted jurisdiction over toothpaste and mouthwash, which are not to be swallowed, and has asserted limited jurisdiction over fluoridated bottled water. See Appendix D-37. But the FDA has not asserted jurisdiction over the fluoride tap water drug.

The City argues that the Initiatives are illegal because they attempt to require the FDA to take certain actions. This is quite a misinterpretation! The Initiatives do not require the FDA to do anything. They simply say there will be no fluoride or other medicines added to City water unless and until they are approved by the FDA. If they are never approved, then the City will never add them.

It was in 1974 that 42 USC 300g-1(b)(11) was added to the SDWA. See page 10 above. Recall that it specifically forbad the EPA from requiring "the addition to drinking water of any substance for preventive health care purposes unrelated to contamination of drinking water."

However, in 1979 the FDA and the EPA entered into an inter-agency treaty, a Memorandum of Understanding, numbered MOU 225-79-2001, attached and labeled as Appendix D-39, in which the agencies agreed that the FDA would

... control bottled drinking water and water, and substances in water, used in food and for food processing....

On the other hand, the EPA would

"... take appropriate measures, under the SDWA and/or TSCA [Toxic Substances Control Act], and FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act], to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substance which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances. [emphasis added]

There were two problems with this deal. First, only Congress can change a federal statute. Agencies cannot cede their authority to each other. Second, the FDA was ceding to the EPA all its authority "to control direct additives to drinking water." However, the EPA had been prohibited in 1974 from creating any regulations which require adding any "substance for preventive health care purposes unrelated to contamination of drinking water." The FDA might theoretically have

had the power to regulate medication of water, but it could not assign such power to the EPA. It was a role the EPA was barred from filling.

The net result was that the FDA was unwilling to regulate and the EPA was legally barred from regulating the addition of fluoride to drinking water, although the illegal treaty made it appear that the EPA could do so.

In 1985 the EPA assigned to a trade association known as NSC the EPA's authority to write regulations governing the addition of fluoride to drinking water. The EPA did not own the powers it assigned.

Who or what is NSF? See Appendix D-46, a July 7, 2000, letter from Stan Hazan, then NSF general manager, to Rep. Ken Calvert:

NSF involvement in the evaluation of drinking water chemicals, including fluoride-based chemicals, began in 1985, when the U.S. EPA <u>granted</u> an NSF-led consortium of stakeholders the responsibility to develop consensus, health-based, quality specifications for drinking water treatment chemicals and drinking water system components. [emphasis added]

NSF proceeded to construct the NSF Standard 60 rule. The "NSF 60" logo is stamped on every fluoride shipment bill of lading. The Hazen letter continues:

"NSF 60 Drinking Water Treatment Chemicals – Health Effects" was initially adopted in December 1987, and was last revised in May 2000. The standard was developed using a consensus standards development process with representation of the major stakeholder interests, including product manufacturers [emphasis added].... Id., Appendix D-47.

So the industries which produce fluosilicic acid are on the board which developed the standards that regulate fluosolicic acid. Hazan's letter contains contradictory statements regarding testing of the fluoride product:

The standard requires that the manufacturer of a product submitted for certification provide <u>toxicological information</u>, <u>if available</u>. NSF requires that manufacturers seeking certification to the standard submit this information as part of their formulation or ingredient supplier submission. ... Emphasis added. Id., Appendix D-48.

Toxicological studies are to be provided by the fluoride manufacturers <u>if</u> such studies are available. Even if such studies are provided, the public is not allowed to read them:

Individual test reports, as well as formulation information are protected by nondisclosure agreements with certification clients. Id., Appendix D-48.

NSF took over fluoride regulation from the EPA but NSF Standard 60 is a private document. To read it you must buy it for \$325. http://www.techstreet.com/cgibin/results. Most water departments do not even posses a copy the Standard 60 book. Nevertheless, WAC 246-290-220(3) requires water districts to conform to Standard 60.

The EPA lacked authority to regulate the <u>addition</u> of fluoride to drinking water, but the EPA set up the NSF, and NSF right away wrote Standard 60 and started regulating the <u>addition</u> of fluoride to drinking water.

Note that NSF follows the EPA 4 ppm Maximum Contaminant Level for fluoride:

NSF has based its certification on the product use not exceeding the EPA's MCL [maximum contaminant level] for fluoride. ...

NSF was using the EPA 4 ppm MCL for a purpose for which the EPA could not use it, that is for the <u>addition</u> of fluoride to drinking water. Maybe this shows that the people running NSF do not understand what the SDWA does not allow. Hazen continues:

Contaminants in the finished drinking water are not permitted to exceed one-tenth of the EPA's regulated MCL (Maximum Contaminant Level) when the product is added to drinking water at its Maximum Use Level, unless it can be documented that a limited number of sources of the contaminant occur in drinking water. ... Id., Appendix D-48.

This shows again that NSF does not follow its own rules. Instead of setting a .4 ppm MAL, maximum allowable level, which would be one-tenth of the EPA 4.0 ppm MCL, NSF sets a 1.2 ppm MAL and justifies it in this way:

An MAL of greater than 10% of the MCL can be established by the certification body in limited cases if it can be reasonably documented that there are no other significant sources of the same contaminant, that together, would result in the finished drinking water contaminant concentration exceeding the MCL. Fluoride has an MAL of 1.2 mg / liter, which is 30% of the MCL. This is justified on the basis of the limited number of other potential sources of fluoride ion to drinking water. For example, water that naturally contains sufficient fluoride is not additionally fluoridated, and fluoride is seldom present in other additives. Id., Appendix D-52.

The justification given is that there are no other sources of fluoride that add to the 30 percent load. However, there are many other sources of fluoride besides the fluoride added to drinking water, the greatest being common fruits, grains, beverages, and toothpaste accidentally swallowed, especially by children under two. The Environmental Working Group notes, for example, that there is up to

900 ppm of fluoride in dried eggs and that one-third of all eggs are dried and then added to food products. See Appendix D-54. Grains are fumigated with sulfuryl fluoride to kill weevils, and the grain is fed to the chickens.

See 2006 NRC Report at 20. Appendix D-53. See Wikipedia article on sulfuryl fluoride attached as Appendix D-56.

The February 2008 NSF Fact Sheet on Fluoridation Chemicals says:

The NSF Joint Committee ... consists of ... <u>product manufacturing representatives</u>. ... Standard 60 ... requires a <u>toxicology review</u> to determine that the product is safe at its maximum use level and to evaluate potential contaminations in the product. ... A <u>toxicology evaluation</u> of test results is required to determine if any contaminant concentrations have the <u>potential to cause adverse human health effects</u>. ... NSF also requires <u>annual testing and toxicological evaluation</u> The NSF standard requires ... <u>toxicological evaluation</u>. ... Appendix D-59.

It is hard to prove something does <u>not</u> exist, but there is evidence that there are no toxicological studies. First, there are no toxicological studies of fluoride on the extensive NSF web site at <u>www.NSF.org</u>. Blake Stark is the person at NSF International now in charge of fielding questions regarding Standard 60. Call Blake at 734-769-5480 or email him at <u>Stark@NSF.org</u> and ask him if there are any toxicological studies. He is an honest guy. He will tell you there are none. See an example of a Blake Stark response to a request for toxicological studies, labeled as Appendix D-67. See also a transcript of a California deposition in which another NSF official, Stan Hazen, also admits that suppliers are not required to deliver toxicological studies. See Appendix E.

Washington law, WAC 246-290-220(3), requires that

any treatment chemicals with the exception of commercially retailed hypochlorite compounds such as Clorox, Purex, etc., added to water intended for potable use must comply with ANSI/NSF Standard 60.

We are coming full circle now. Municipalities rely on the NSF for certification that the fluoride it buys is not harmful. By law, municipalities must conform to a sham law. Again, the electorate should have the right to vote against enforcement of a sham law, and this by definition makes this issue legislative and not administrative.

Note that the February 2008 NSF Fact Sheet on Fluoridation Chemicals discusses "fluosilicic acid." Fluosilicic acid and hexafluorosilicic acid are the same thing as flurosilicic acid. See Wikipedia article on Hexafluorosilicic acid, Appendix D-68. Note also that it is "fluorosilicic acid" which Port Angeles is adding to city water. See the October 28, 2008, letter from Gregg Grunenfelder of the Department of health to Eloise Kailin, Appendix D-71. Mr. Grunenfelder says:

[W]e rely on national certification protocols to ensure the safety of water additives. Specifically, Washington Administrative Code 246-290-220(3), requires that: "Any treatment chemicals ... must comply with ANSI/NSF Standard 60.... Since the fluoridation product being used by the city of Port Angeles is certified under NSF Standard 60, the city's use of this product is in compliance with state law.

What is fluosilicic acid? The February 2008 NSF Fact Sheet on Fluoridation Chemicals, Appendix D-59, describes this chemical:

[F]luosilicic acid is produced by adding sulfuric acid to phosphate ore. This is typically done during the production of phosphate additives for agricultural fertilizers. ... The most common contaminant detected in these products is arsenic The current MCL for arsenic is 10 ppb, the highest detection of arsenic from a fluoridation chemical was 0.6 ppb The third most common contaminant found is lead ... with 0.6 ppb being the highest concentration detected [emphasis added].

However, the MCLG, the maximum contaminant level goal, for arsenic and lead are both zero. See 40 CFR 141.51, Appendix D-72. These chemicals are so nasty that there is no justification for adding any of them to drinking water. Fluoride is a little more toxic than lead, a little less toxic than arsenic. However, the MCL for lead is 15 ppb; the MCL for arsenic is 10 ppb; but the MCL for fluoride is 4,000 ppb, that is 4.0 ppm. See Appendix D-73, Clin Toxicology Commer Products. The Amici ask the Court to take judicial notice of this.

If there is any doubt regarding the bogus nature of NSF Standard 60 certification, read through the NSF documents again looking for any reference to the 2006 NRC Report. There is none. NSF standards are outdated, and Port Angeles is relying on a sham law that is also outdated.

Tudor Davies, former director of the Office of Science and Technology for the EPA stated in his April 2, 1998, letter to George Glasser, Appendix D-104, the following:

In the United States, there are no Federal safety standards which are applicable to drinking water additives, including those intended for use in fluoridating water. In the past the EPA assisted the States and public water systems through the issuance of advisory opinions on acceptability of many additive chemicals. However, the Federal advisory program was

terminated on October 4, 1988, and <u>EPA assisted in establishment of voluntary product standards at NSF International (NSF)</u> NSF Standard 60 ... was developed by NSF by a consortium of representatives from utilities, government, manufacturers and the public health community. [emphasis added]

So this is how the shell game works. Most people naively assume that the EPA has jurisdiction over drinking water fluoridation through the SDWA. The EPA helped start NSF and gave it legitimacy. The NSF pretends to be authoritative, and pretends to have inherited its authority over fluoride from the EPA, and so people trust it when its fact sheet mentions health, safety, inspections, and toxicology. What is going on is that the NSF is pretending to do what the EPA by law is barred from doing, to authorize and regulate the <u>addition</u> of fluoride to water.

Water commissioners like Grunenfelder are deceived by the shell game.

This is a different kind of shell game. In the old days there was a pea under one of the walnut shells. In this case, there is no pea under any of the shells.

No federal agency is empowered to write regulations which require that fluoride be added to drinking water, so we must ask if there is a Washington agency which does so. The Department of Health is the lead agency for enforcement of the SDWA in Washington, but it is forbidden by the SDWA from writing a regulation requiring the addition to water of "any substance for preventive health care purposes unrelated to contamination of drinking water."

See the page 10 above. Further, the Department of Health does not require the

addition of fluoride to water, it merely says that if a municipality fluoridates, it must follow certain fluoridation practices. WAC 246-290-460. The municipalities make the decision to fluoridate.

XI. FLUORIDE AND FLUORIDATED WATER ARE UNAPPROVED DRUGS

The FDA is very blunt about this:

Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals, is a drug that is subject to FDA regulation.⁹

The FDA policy is that if a drug is intended to treat disease, it meets the definition of a drug. ¹⁰ State law defines drugs as substances intended for use in the . . . mitigation, treatment, or prevention of disease. ¹¹ Thus, both fluoride and fluoridated drinking water are drugs. This is an example of an ignored or unenforced law.

It is the FDA – not the EPA¹² – which approves drugs for marketing – regardless of the method of dispensing the drug or the drug's concentration.¹³

⁹ FDA response to Honorable Ken Calvert, Chairman Subcommittee on Energy and Environment Committee on Science, House of Representatives, Dec 21, 2000 at 1 (Appendix D-101 hereto).

¹⁰ The FDA guidance document in Appendix D-74 states that intent may be established by consumer perception or by ingredients known for therapeutic use such as "fluoride in toothpaste." ¹¹ RCW 69.41.010(9)(b). Appendix D-75.

¹² 42 U.S.C. sec. 300g-1(b)(11)

¹³ FDA response to Honorable Ken Calvert, Chairman Subcommittee on Energy and Environment Committee on Science, House of Representatives, Dec 21, 2000 at 1 (Appendix D-101 hereto).

Since 1938, every new drug has been required to file a FDA New Drug Application (NDA) before U.S. commercialization.¹⁴

The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions: Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks. Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain. Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. ¹⁵

The FDA withdrew approval of a new drug application for the ingestion of fluoridated vitamin supplements, saying "there is no substantial evidence of drug effectiveness as prescribed, recommended, or suggested in labeling." The FDA regulates fluoridated bottled water. D-37.

Washington pharmacy laws regulate legend or prescription drugs. A "legend drug" cannot be sold, delivered, dispensed or administered except by prescription in accordance with RCW 69.41.020. Some of the laws regulating prescription drugs are:

It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician [or other authorized provider]." RCW 69.41.030(1).

A prescription, in order to be effective in legalizing the possession of legend drugs, must be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs." RCW 69.41.040(1).

¹⁴ FDA New Drug Application, Introduction (Appendix A-37 hereto). We request that this Court take judicial notice that community water fluoridation began in the 1940's after regulations requiring NDAs were in place.

¹⁵ FDA New Drug Application, Introduction (Appendix D-77 hereto).

¹⁶ Drug Therapy, June, 1975. See Appendix D-105.

To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date. . . . "RCW 69.41.050(1).

A legend (prescription) drug is misbranded in conflict with RCW 69.04.470 if there is not prominent labeling; in conflict with RCW 69.04.490 if active and certain inactive ingredients are not listed; in conflict with RCW 69.04.500 if there are not adequate warnings of possible dangerous use; in conflict with RCW 69.04.520 if it can be dangerous to health; and in conflict with RCW 69.04.540 if a legend drug is dispensed at retail without a written prescription. When the City delivers fluoridated water, it is running afoul of the above laws. Citizens have a right to vote to stop such illegal acts, and thus for another reason this issue is legislative and not administrative.

VII. WHERE DOES FLUORIDE COME FROM?

Christopher Bryson describes how fluoridation came about in his masterful book, The Fluoride Deception which will be summarized briefly.

Fluoride can come from aluminum and steel plants, where it is used as a flux to lower the melting point of the metal. It is used in great quantity to produce uranium because fluorine dissolves uranium to produce uranium hexafluoride.

Fluoride was essential to winning World War II. After the War, the biggest source of fluoride has been the production of super-phosphate fertilizer.

To produce phosphate fertilizer that can be quickly absorbed by plants, raw phosphate ore must be processed to produce commercial phosphate fertilizer. Phosphate ore contains heavy metals such as lead and uranium as well as arsenic and is around 4% fluoride. Sulfuric acid is added to the ore. Clouds of fluoride gasses are produced. In the past the gasses were vented up the smokestack, and entire counties were poisoned by the fluoride fumes. The government participated in cover-ups. Fluoride became a "protected pollutant."

Today the fumes must pass through scrubbers, which capture most of the fluoride along with the heavy metals. The condensate liquid is called scrubber liquor, the leftovers. With no filtration or any further processing, it is put in tankers and shipped to thousands of water districts around the country, including Port Angeles. Fluorides added to drinking water are the unprocessed scrubber liquor left over after phosphate fertilizer, aluminum, steel, or uranium is produced. It is filth. Although it is diluted 240,000 times, from 24% down to 1.0 ppm, it is still filth.

The phosphate fertilizer industry is itself a pollution nightmare. In addition to producing millions of gallons of fluoride, it also yields millions of tons of useless left over "gypsum." Gypsum is mostly silicon. This pretty white small gravel gypsum would be perfect for building roadbed foundations, but

unfortunately it is radioactive. Gypsum is dredged from settling ponds as the water evaporates out and is stacked in gigantic gypsum piles a hundred feet high which surround cooling ponds which extend over areas the size of cities. The piles will probably remain there for eternity. The EPA accepts indefinite disposal onsite as an accepted way to deal with the toxic waste. There is probably nothing that can ever be done with the liquid or solid waste. Industry does not buy it because it contains too much silicates. See the attached Appendix D-81 entitled Bone Valley, an article from Wikipedia describing one region where phosphate fertilizer and fluoride are produced.

Unfortunately, a sink hole opened up under a gypsum pile in Florida, and thousands of tons of untreated scrubber liquor fell into the Florida aquifer, permanently polluting the river of water that runs under the state. See photos attached and labeled as Appendix D-86. See Phosphate Fertilizer Industry: An Environmental Overview, Appendix D-88 for more scandalous information about the phosphate fertilizer industry. For a satellite's eye view of wreckage in another area go to http://maps.google.com and do a search for "Purvis Still White Springs Florida." Click on "satellite" view.

Further clarifying the enormity of this tragedy is the simple fact that the superphosphate fertilizer industry is unnecessary. Its product is designed for growing corn, wheat, and cotton as fast as possible. The problem with superphosphate fertilizer is that it builds up in the soil and deadens microbial life.

Organic farmers use ordinary ground up rock phosphate which they compost in animal or plant manure. It takes more time and is more work, but the end result is healthier soil and healthier plants. See Phosphate Rich Organic Manure, Appendix D-97.

XIII. WHY DO WE FLUORIDATE?

Bryson explains that just as there were captains of industry and public relations experts who convinced us that cigarettes, asbestos, tetraethyl lead, and DDT were good for us, there were leaders in the aluminum industry who believed that naturally occurring calcium fluoride reduced caries but who also had excess fluoride to sell. The Mellon Institute, which had promoted asbestos and tetraethyl lead, long after its leaders knew they were harmful, promoted fluoride in the same way. Edward Bernays, nephew of Sigmund Freud, probably the first true public relations expert, the man who convinced women to take up cigarette smoking, also promoted drinking water fluoridation. There was a lot of toxic fluoride waste to get rid of, and there was money to be made. Rebecca Hanmer, EPA official, stated in 1983:

In regard to the use of fluosilicic acid as a source of fluoride for fluoridation, this agency regards such use as an ideal environmental solution to a long-standing problem. By recovering by-product fluosilicic acid from fertilizer manufacturing, water and air pollution are minimized, and water utilities have a low-cost source of fluoride. Rebecca Hanmer, Letter to Leslie Russell, 1983, See Appendix D-99.

Port Angeles pays around \$520 per ton for this chemical. See Appendix D-100, a Lucier Chemical Industries invoice for a 12 ton load that cost the City \$6,214. Fluoride producers turn a waste product into a profit center. Bryson estimates that 200,000 tons of fluoride is sold yearly for drinking water fluoridation. That adds up to a \$104 million per year industry. Bryson tells how fluoride promoters made large donations to dental schools, and certain dentists became their best lieutenants. (Scholarly dentists are among fluoridation's most active opponents.)

Opposition to fluoridation has been muted. Bryson tells how researchers who found evidence fluoride was harmful were denied research funding, driven from academic positions, and lampooned as kooks. Back in the 1950s the John Birch Society opposed fluoridation as a communist conspiracy. The Birchers were derided as paranoid conspiracy theorists, and scientific opponents were classed with the Birchers and thus marginalized.

XII. CONCLUSION

Fluoridation offers no benefit and causes much harm. It is expensive. It is hazardous to handle. Manufacturing it produces miles of toxic waste which cannot be cleaned up. It is absurd that we are arguing about the right to vote on fluoridation as opposed to the abolition of this vice. There is a lot of money in fluoride, so it is highly addictive to corporations which have low environmental morality and thus hard to overcome.

The Washington Supreme Court is the constitutional court of this state. Its primary duty is to protect the constitutional rights of the citizens. The Amici ask this Court to acknowledge the common law, statutory, and constitutional issues raised in the Initiatives, to consider them, to decide in favor of the Committees, and to order that the Initiatives be put on the ballot immediately so the citizens can vote on this important issue. In the alternative, the Amici ask the Court to remand this case to the Trial Court for a full hearing of the issues.

Dated this 10th day of February, 2010.

Respectfully submitted,

James Robert Deal, WSBA No. 8103

Attorney for Amici



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

APR 2 1998

OFFICE OF WATER

George C. Glasser 3016 23rd Street N. St. Petersburg, FL 33713

Dear Mr. Glasser:

Your March 4, 1998, letter to Carol Browner regarding the need for research on fluorosilic acid was forwarded to the Health and Ecological Criteria Division (HECD) of Office of Science and Technology (OST) at the Office of Water (OW). The Environmental Protection Agency (EPA) appreciates your interest in this matter.

In the United States, there are no Federal safety standards which are applicable to deinking water additives, including those intended for use in fluoridating water. In the past, the EPA assisted the States and public water systems through the issuance of advisory opinions on acceptability of many additive chemicals. However, the Federal advisory program was terminated on October 4, 1988, and EPA assisted in establishment of voluntary product standards at NSF International (NSF) in Ann Arbor, Michigan. American National Standards Institute (ANSD/NSF Standard 60: Drinking Water Treatment Chemicals – Health Effects was developed at NSF by a consortium of representatives from utilities, government, manufacturers and the public health community. The first edition of the Standard was issued in 1988. Standard 60 applies to all direct additive chemicals for potable water including sodium fluoride, hydrofluosilicic acid and sodium fluosilicate. At the present time, both NSF and Underwriter's Laboratories (UL) evaluate additive products against Standard 60 criteria and publish a listing of those products that meet the requirements of the Standard. You can contact NSF or UL for information on specific fluosilicate products.

EPA does receive many requests for information on the fluosilicate additives. Accordingly, EPA is in the process of conducting a literature search and review of the data available on the health effects and chemistry of these materials. This project should also identify research needs. It is anticipated that the review of the available data will be completed by this coming Fall. EPA plans to use the data collected to prepare a fact sheet that can be sent to citizens, like yourself, who request information on the fluosilicate additives used in fluoridation. EPA will also share the information collected with the Chemical Manager for Fluoride at ATSDR and with NSF International.

If you have any further question on this matter, please feel free to contact Dr. Joyce Donohue at 202-260-1318.

SINCELEDY

Tudor T. Davies, Director

Office of Science and Technology

N-104



NDA withdrawn for fluoride and vitamin combinations

The FDA has addressed a "regulatory letter" to approximately 35 companies marketing combination drugs consisting of fluoride and vitamins. The letter states that these drugs are related to a product (Enziflur lozenges) for which FDA has withdrawn approval of a new drug application. The NDA for Enziflur was withdrawn because the rest of supering the control of the state of the sta

The FDA has therefore advised manufacturers of combination fluoride and vitamin preparations that their continued marketing is in violation of the new drug provisions of the Federal Food, Drug, and Cosmetic Act; they have, therefore, requested that marketing of these products be discontinued.

DRUG THERAPY/JUNE 1975

D-105